

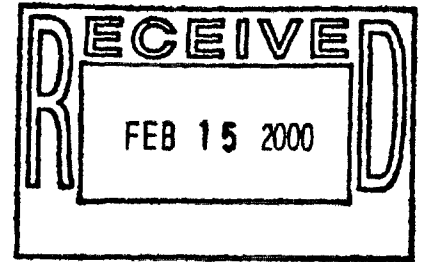
EMORD & ASSOCIATES, P.C.

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February 11, 2000

VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

***Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93***

Dear Dr. Yetley:

Pure Encapsulations, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Pure Encapsulations, Inc. retains scientific documentation supporting the statements.

1. Supplement Brand Name (ingredient)

Cholesterex or CholestePure (beta-sitosterol, campesterol, stigmasterol, and brassicasterol)

Text of Statements of Nutritional Support

Promotes proper cholesterol absorption.

Beta sitosterol enhances the versatility of this formula, providing specific support for a healthy immune response.

In addition, it has been shown to promote healthy prostate and urinary function and to maintain cellular health for the colon.

Beta-sitosterol contained in this formula may also support immune, prostate, and colon cell health.

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¹ The address for Pure Encapsulations, Inc. is 490 Boston Post Road, Sudbury, MA 01776.

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2. Supplement Brand Name (ingredient)

Growth Hormone Support (ornithine alpha-ketoglutarate (OKG) and arginine)

Text of Statements of Nutritional Support

Supports healthy growth hormone levels.

The amino acids arginine and ornithine have been shown to synergistically support healthy growth hormone secretion.

It stimulates muscle protein synthesis, moderates the break down of muscle tissue, promotes fat utilization for energy, and supports healthy immune responses.

Ornithine alpha-ketoglutarate has demonstrated the ability to enhance healthy insulin activity and nitrogen balance, energizing working muscles.

OKG promotes healthy polyamine, arginine and glutamine levels, important metabolites for muscle protein support.

In addition, OKG helps active healthy immune cell function after physical stress, maintaining healthy muscle tissue.

Taken one hour before physical activity or bedtime, arginine and OKG promote natural growth hormone production and optimal muscle metabolism, supporting endurance and strength training healthy muscle recovery and lean muscle mass.

3. Supplement Brand Name (ingredient)

FibroMalic (malic acid, magnesium, and l-carnitine)

Text of Statements of Nutritional Support

Enhanced muscle energy support.

Malic acid and magnesium provide synergistic support for energy production.

l-Carnitine is also crucial for mitochondrial production of ATP in skeletal muscle and enhances the ability of muscle to sustain energy and proper function by supporting healthy oxygenation of tissue.

A recent study suggests that a combination of malic acid and magnesium nutritionally supports energy and muscle health in volunteers.

Pure Encapsulations Malic Acid Plus offers a novel, enhanced energy support formulation for rejuvenating energy and muscles.

4. Supplement Brand Name (ingredient)

ODex (champignon (*Agaricus bisporis*) extract)

Text of Statements of Nutritional Support

Modifies oppressive odors, supports the intestine, kidney and liver.

Champignon extract has demonstrated the ability to modify breath, body and gastrointestinal odor, and to support microflora balance, intestinal activity, and renal health.

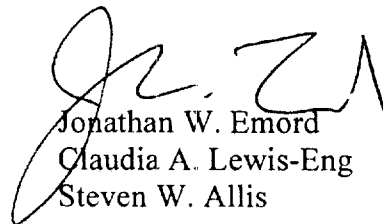
Furthermore, a study with champignon extract revealed that it also promotes proper levels of creatinine, providing additional renal support.

For these reasons, it is believed to help detoxify both the kidney and the liver.

Champignon extract has demonstrated the ability to moderate the formation of indoleacetic acid, tryptamine, ammonia, methylmercaptan, hydrogen sulfide and amines, helping the body to naturally deodorize and to maintain healthy intestinal, renal and liver function.

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,



Jonathan W. Emord
Claudia A. Lewis-Eng
Steven W. Allis

Attachment

Certification

I, Ray Hamel, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on: February 7, 2000

Raymond F. Hamel
Ray Hamel

2000-0000

Feb

Manager of Pure Encapsulations
going to be truthful and not misleading

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